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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
03-0116 (US01)

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on April 15, 2005

Signature /NancyRushton/

Typed or printed name Nancy Rushton

Application Number	Filed
10/695,151	October 27, 2003

First Named Inventor
Stephen Porter

Art Unit	Examiner
3731	Elizabeth Houston

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 37,104

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/DavidTBurse/
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April 15, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	**Group Art Unit:** 3731
Stephen Porter	**Confirmation No.:** 6462
Serial No.: 10/695,151	**Examiner:** Elizabeth Houston
Filed: October 27, 2003	
For: VASO-OCCLUSIVE DEVICES WITH IN-SITU STIFFENING ELEMENTS	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully requests a pre-appeal brief conference. No amendments are being filed with this request. Therefore, claims 1-16, 20-30, 32-38 and 40-42 remain pending in this application. Claims 1-8, 14-16, 20, 21, 24, 27, 30, 34-36 and 40-42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,193,728 ("Ken") in view of U.S. Patent No. 5,669,931 ("Kupiecki") in further view of U.S. Patent No. 7,066,904 ("Rosenthal"). Claims 9-13, 22-26, 28, 29 and 36-38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view Kupiecki, in view of Rosenthal and in still further view of US Publication No. 2001/0046518 ("Sawhney"). Applicant respectfully traverses these rejections.

Independent claim 32 is included on the Summary of the Final Office Action ("FOA") as one of the rejected claims, but there is no explanation provided in the body of the FOA that addresses a rejection of claim 32. For purposes of this paper, Applicant is assuming the Examiner intended to reject claim 32 on the same grounds as the rejections of the other claims, and Applicant's remarks herein are also directed to claim 32.

According to the FOA, Ken discloses the device as claimed, assuming that the stretch resistance member in Ken is read on the "active element" limitation, except that the stretch resistance member does not contract. According to the Examiner, it would have been obvious in view of Kupiecki and Rosenthal to incorporate a hydrogel carrying

a drug within the lumen of an occlusive coil, wherein the hydrogel "[radially] contracts" in situ to release the drug; and wherein the hydrogel would be applied as a coating over the stretch-resistance element of Ken in order to meet the "active element" limitation. Applicant respectfully submits that this conclusion of the Examiner (i) does not support a prima facie case of obviousness; and (ii) is not factually realistic in view of the actual teachings of these references.

Independent claims 1, 30, 32 and 40 each recite an active element (claims 1, 32 and 40) or hydrogel member (claim 30) having a pre-deployment configuration carried entirely within the lumen defined by a vaso-occlusive member, wherein the active element or hydrogel **contracts**, without the application of mechanical force, to a deployed configuration that **causes the occlusive member to substantially retain its shape** (claims 1, 30 and 32) or to stiffen (claim 40) when deployed in a body cavity (claims 1 and 40) or vasculature (claims 30 and 32).

Ken discloses a vaso-occlusive coil with a stretch resistant member (108, 214) disposed within its lumen, which according to the FOA (page 2) is considered by the Examiner reads on the claimed "active element". The stretch resistance member of Ken prevents stretching of the vaso-occlusive coil by having the stiffness necessary to hold the coil in place. However, Ken does not disclose that the stretch resistance member contracts, as acknowledged by the Examiner, to thereby cause the occlusive member to substantially retain its shape when deployed in a body cavity. In particular, the stretch resistance member of Ken does not contract with or without application of mechanical force. Neither Kupiecki nor Rosenthal supply these missing features of the claims.

Kupiecki discloses a flexible occlusive implant/coil having a proximal portion that fold upon itself (e.g. ball-like mass) and maintain such configuration without resistance, when deployed. The coil interior may be filled with drugs material and have the ends partially sealed for slow drug released from the coil. (Col. 2, lines 47-64, Col. 6, lines 11-17). Rosenthal discloses a balloon catheter comprising a hydrogel coating on its outer surface. The hydrogel carries a drug that is released from the hydrogel when the hydrogel is exposed to a triggering agent, causing the hydrogel to contract and the drug to be squeezed out of the contracted hydrogel. (Col 1, line 47 to Col 2 line 57, Col 6, lines 55-64, Fig 4).

Even if a person skill in the art were to combine the teachings of Ken, in view of Kupiecki and Rosenthal, the resulting device would be a vaso-occlusive coil (of Ken) having a drug material in the interior of the coil with the coil's ends partially sealed (Kupiecki), but not in the lumen formed by the coil, and not in the stretch resistance member) and/or having a hydrogel coating that carries drugs in the outer surface of the coil (Rosenthal) where the coating may contract to squeeze out drugs to be delivered to the wall of blood vessels when exposed to a triggering agent, in view of the teachings of the cited references. However, such combination of these references will not produce a device having an active/hydrogel element that contracts without the application of mechanical force to cause the occlusive member to substantially retain its shape.

It is respectfully submitted that the FOA does not set forth an adequate basis (based on evidence or scientific reasoning; See BPIA decision in ex parte Whalen) that shows how a person of ordinary skill in the relevant field would have been prompted to combine the respective teaching of Ken, in view of Kupiecki and Rosenthal, in the fashion recited in the claims involved in this pre-appeal, absent hindsight of the present application.

Applicant does not concede that the references may be properly combined in the manner set forth in the FOA, but even if it would be somehow obvious to one of ordinary skill in the art to apply the coating of Rosenthal on the stretch resistance member of Ken, the materials used in constructing the stretch resistance member of Ken are metals or their alloys *"tailored to accomplish and appropriate blend of flexibility and stiffness"* (Ken, Col 5, lines 17-28) which prevents "stretching of the coil during movement of that coil" (Ken (57) lines 10-11). The stretch resistant member of Ken would be able to bend with the bending of the occlusive member and would be able to maintain its stiffness after the occlusive member it is positioned in the body. It is factually incorrect and not consistent with the disclosure of Ken that its stretch resistance member would contract just because a hydrogel coating is incorporated onto or into the stretch resistance member. In other words, the hydrogel coating may itself contract but not the stretch resistance member, and it is the stiffness of the stretch resistance member that retains the shape of the coil after delivery, not the hypothetical hydrogel coating of Rosenthal.

The Examiner further states that *"the claimed invention only requires that the final product of a contracted active element/hydrogel causes the coil to retain its shape since it is after the act of contracting and reshaping the coil that the active element causes the coil to retain its shape"* (FOA, page 4). Whether or not the Examiner's interpretation of the independent claims is correct, contraction of the stretch resistance member of Ken is not possible, even if combined with the drugs or hydrogel of Kupiecki and Rosenthal. The drugs of Kupiecki would be in the interior of the coil of Ken (not in the lumen) and the hydrogel coating would be in the outer surface of the coil of Ken (not in the stretch resistance member). Only using improper highlight would it be apparent to consider applying the hydrogel coating over the stretch resistance member, and even so, a contracted coating over the stretch resistance member will cause the release of drugs but will not cause the coil to substantially retain its shape, as required by independent claims 1, 30, 32 and 40.

Claims 9-13, 22-26, 28, 29 and 36-38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken, in view Kupiecki, in further view of Rosenthal, and in still further view of US Publication No. 2001/0046518 ("Sawhney"). Applicant respectfully traverses this rejection, since the combination of the above-identified four separate references does not disclose or suggest the elements required by these claims.

Sawhney discloses methods for hydrating (expanding) hydrogel in situ, which releases therapeutic agents to a body to promote sealing or augmentation of tissue or vessels (Paragraphs 22, 26, 104). Sawhney also discloses different types of hydrogels. As discussed above, however, a combination of Ken in view of Kupiecki and Rosenthal will not produce an occlusive device with an active element that contracts to cause the occlusive member to substantially retain its shape when deployed in a body cavity or vasculature site. Modifying Ken in view of Kupiecki and Rosenthal and Sawhney will still not render the claimed device, since further modifying the device in view of Sawhney would produce expansion, not contraction, of the hydrogel (regardless of the type) in-situ.

Claims 9-13, 22-26, 28 and 29 incorporate all of the elements and limitations of independent claim 1, and claims 36-38 incorporate all of the elements and limitations of independent claim 32, and therefore are allowable for at least the same reasons

For at least these reasons, Applicants respectfully submit that the FOA has not set forth a prima facie case that independent claims 1, 30, 32 and 40, and their respective dependent claims 2-8, 14-16, 20, 21, 24, 27, 34-36, 41 and 42, are unpatentable as being obvious over Ken in view of Kupiecki and in further view of Rosenthal, or that dependent claims 9-13, 22-26, 28 and 29 are unpatentable over the same combination of references, plus the addition of Sawhney.

CONCLUSION

For the reasons set forth above, Applicant respectfully submits that currently pending claims are patentable over the cited prior art. A notice of allowance is respectfully requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: April 15, 2009 By: /DavidTBurse/
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